

K962007

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(K) CONTACT: Cheryl Hastings
Manager, Clinical Affairs

TRADE NAME: DePuy Protrusio Cages

COMMON NAME: Surgical Mesh

CLASSIFICATION: 878.3300 Surgical Mesh

DEVICE PRODUCT CODE: 78 JDJ

**SUBSTANTIALLY
EQUIVALENT DEVICES:** DePuy Protrusio Rings

INTENDED USE AND DEVICE DESCRIPTION:

The DePuy Protrusio Cage is intended to be used to reinforce a deficient or weakened medial acetabular wall to prevent the protrusion of an acetabular cup prosthesis into the abdominal cavity and may be indicated for use in cases involving acetabular revision procedures, severe osteoporosis, Protrusio Acetabuli, or a shallow acetabular roof.

The DePuy Protrusio Cage is a rimmed metal shell with multiple holes and iliac and ischial "wings". It is intended to reinforce weak acetabula by transferring stress away from the medial wall to the stronger acetabular rim. The wings and rim of the cage can be fixed to solid bone using Titanium bone screws. The reinforcement provided by the Protrusio cage allows improved fixation of an acetabular cup prosthesis, which can be fixed inside the Protrusio cage using bone cement. The DePuy Protrusio cage is available in diameters of 52, 56 and 60mm in right and left configurations. The Titanium bone screws have a diameter of 6.5mm and are available in lengths of 20, 25, 30, 35, 40, 45, 50, 55 and 60mm.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Protrusio Cages are similar to the Protrusio Rings that were sold by DePuy prior to 1976. Like the pre-enactment Protrusio Rings, the Protrusio Cages are intended to reinforce weak acetabula. The Protrusio Rings were manufactured from Protasul 10 Co-Ni-Cr-Mo and the design consisted only of a rim with flanges which extended into the acetabulum. The Protrusio Cages are manufactured from Ti-6Al-4V, have more of a domed shell that extends into the acetabulum and have iliac and ischial wings which help fix the cage to the rim of the acetabulum.